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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/710,923	08/12/2004	Melissa Vass	158982 (GEM0053USP)	4922

23413 7590 01/12/2009  
CANTOR COLBURN, LLP  
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EXAMINER
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CWERN, JONATHAN

ART UNIT	PAPER NUMBER
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3737

NOTIFICATION DATE	DELIVERY MODE
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01/12/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptopatentmail@cantorcolburn.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/710,923	<b>Applicant(s)</b> VASS ET AL.	
	<b>Examiner</b> Jonathan G. Cwern	<b>Art Unit</b> 3737	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 December 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 and 16-47 is/are pending in the application.
- 4a) Of the above claim(s) 16-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 46-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 and 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keidar (US 6650927) in view of Subramanyan et al. (US 6782284), Chen et al. (WO 96/10949), and Vesely et al. (US 6246898).

Keidar discloses a system and method for generating a 3D model for use in cardiac interventional planning procedures (such as ventricular pacing planning or atrial fibrillation planning) including everything except for a database, and operator interface

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and a post-processing system for inserting a geometrical marker and selecting a viewable parameter. See Figure 1, 6, and 7, and elements 48 and 49.

Subramanyan et al. disclose a method and apparatus for interventional procedure planning (such as placement of a stent) using a user interface (44) and a post-processing system (40, 48) for marker (72, 280) placement and viewable parameter selection (Figures 9-11). Subramanyan also disclose saving a viewable image, anatomical landmark, etc. (34, 46) to be exported to user interface (44). See Figure 1. Subramanyan further disclose wherein the post processing software further performs image rendering (242) and vessel tracking along a centerline (82). It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to employ the user-interface and post-processing software of Subramanyan et al. in the invention of Keidar to enable vascular tracking and visualization in 3D from multiple directions (Subramanyan, column 2, lines 25-27) and to allow intuitive graphical feedback and interaction with the physician (Subramanyan, column 2, lines 39-42) when administering treatment in tricky regions of the heart which are difficult to mentally visualize (Keidar, column 1, lines 12-27). Furthermore, although Subramanyan disclose saving the image data, a database is not addressed explicitly.

Chen et al. disclose a system and method for anatomical visualization of structures demonstrating that image databases (e.g., 10) are well known and can be used for independently manipulating data and to generate images from a wide variety of viewing positions (see pages 16-18). It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to employ a database as taught by Chen

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et al. in the invention of Keidar in view of Subramanyan et al. as is well known in the art and for the above described reasons.

Vesely et al. disclose a method for carrying out a medical procedure using a three-dimensional tracking and imaging system. Vesely et al. teach locating a navigating an interventional tool using three-dimensional image data. The tool contains several transducers which can be tracked. Additional reference transducers are also located on or in the patient (anatomic landmarks). The tool can be moved within the patient and 3-D coordinate data can be collected of the patient's organ. These reference transducers (markers) can be used to register 3-D image data of the patient with the coordinate system. This results in a model of the patient's organ and the tool, which the physician can then accurately guide within the body (column 15, line 25-column 16, line 53).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used the combined system of Keidar et al., Subramanyan et al., and Chen et al. for location and navigation of an interventional tool as taught by Vesely et al. The use of imaging systems and tracking systems during interventional procedures is old and well known in the art. Navigation of the interventional tool allows for the physician to accurately move the tool within the patient. The imaging data must be registered with the position of the tool for the data to aid the physician in guiding the tool, and the use of markers is a common technique. Other techniques for registering the image data and position data are also well known and would be suitable for use in such systems.

### ***Response to Arguments***

Applicant's arguments filed 12/17/08 have been fully considered but they are not persuasive.

In regards to applicant's arguments regarding the 103 rejection of Keidar in view of Subramanyan et al., Chen et al., and Vesely et al., examiner respectfully disagrees. Applicant argues that Vesely et al. do not teach anatomical landmarks. However, it is clear from Vesely et al., column 13, lines 15-22, that the reference transducers can be located to provide an internal reference frame inside a patient's body or on the surface of a patient body to provide an external reference frame. As stated in the rejection, these are considered anatomic landmarks, as the reference transducers are located on or in the patient.

Applicant then goes on to make various statements that these reference locations **could** introduce variability and motion, the operator is therefore limited to visualizing only that anatomical pathway over which the tool has traveled, and various data may be lost resulting in false security to the operator. First, it should be noted that nowhere in Vesely et al. is this stated, that data may be lost resulting in false security to the operator. Furthermore, applicant's use of the word "could" indicates simply one imagined scenario by the applicant of how this device could fail, and no evidence that such a scenario actually takes place when using this device.

Applicant further argues that the instant invention uses an image which is pre-acquired and not limited to the pathway over which the tool travels. However, in Vesely et al., an imaging modality system acquires 3D image data sets to provide a template

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against which the shape, position, and movement of the instrument can be tracked or displayed (column 13, lines 55-67). These are also pre-acquired image data, and therefore examiner fails to see a difference.

In addition, the Vesely et al. reference is one of many references which could be relied on to teach locating and navigation of an interventional tool. As indicated in the rejection, the use of imaging systems and tracking systems during interventional procedures is old and well known in the art. The use of image data for locating and navigating an interventional tool is not a novel concept.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The 103 rejection involving the Okerlund reference has been withdrawn in view of applicant's arguments.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/  
Examiner, Art Unit 3737

/Ruth S. Smith/  
Primary Examiner, Art Unit 3737



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